UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE NATIONAL PRESCRIPTION OPIATE LITIGATION	MDL No. 2804
This document relates to: *Track One Cases*	Case No. 17-md-2804
	Hon. Dan Aaron Polster

GENERIC MANUFACTURERS' REPLY MEMORANDUM IN SUPPORT OF MOTION FOR PARTIAL SUMMARY JUDGMENT

TABLE OF CONTENTS

TABLE OF AUTHORITIES

CASES **PAGE(S)**

Statutes

Other Authorities

I. INTRODUCTION

Three things are clear from Plaintiffs' Opposition. First, Plaintiffs acknowledge that any claims against Generic Manufacturers[1] based upon their alleged failure to disclose the risks of their generic medicines—or to correct statements by others—are preempted as a matter of law.[2]

Second, while Plaintiffs insist that Generic Manufacturers are liable because they allegedly engaged in "misleading marketing," Opp. at 1, their Opposition fails to create a genuine issue of material fact as to that issue. As to many of the Generic Manufacturers, Plaintiffs cite literally ***zero instances*** of marketing. For the remainder, Plaintiffs fail to identify any marketing that could be characterized as "misleading" with respect to their generic opioid medicines. This is not surprising: the Federal Trade Commission ("FTC"), Food and Drug Administration ("FDA"), numerous courts, and witnesses in this case—including Plaintiffs' experts—have all confirmed that given their unique business model and drug substitution laws, generic manufacturers have no incentive to, and do not, promote the safety or efficacy of their generic medicines.[3]

Plaintiffs' Opposition fails to acknowledge that critical fact—much less explain how any marketing-based claim can proceed in the absence of any false marketing by Generic Manufacturers, which simply sold FDA-approved medicines in volumes expressly permitted by the DEA. Rather, Plaintiffs lump the Generic Manufacturers with entirely separate brand manufacturers and try to make this motion about the promotion of brand medicines. But this motion concerns generic medicines, and Plaintiffs' own evidence shows that ***no Generic Manufacturer ever marketed the safety or efficacy of its generic medicines in Ohio or elsewhere***. To the contrary, the evidence Plaintiffs cite confirms that any marketing activity by Generic

---

[1] All party naming conventions follow the definitions set forth in footnote one of the opening memorandum.
[2] *See* Pls.' Opp. to Generic Mfrs.' Mot. for Partial Summ. J. ("Opp."), PSJ8, Dkt. No. 2436, at 3 ("Plaintiffs do not assert that the Generic Defendants should have made labeling changes."); *id.* at 26 (same).
[3] *See* Generic Mfrs.' Mem. In Support of Mot. for Partial Summ. J. ("Mem."), Dkt. No. 1860-2, at 2-9.

Manufacturers as to their generic medicines—even in the few instances where some contacted prescribers—was limited to innocuous statements about those medicines' availability, price, and/or bioequivalence. Plaintiffs have not identified anything false about those statements.

Third, Plaintiffs make no effort to and cannot satisfy their burden of showing that marketing by the Generic Manufacturers caused any improper opioid prescriptions. Plaintiffs have insisted throughout this litigation that they will prove causation through aggregate evidence. But they have not attempted to offer such evidence as to Generic Manufacturers. Their primary causation expert, Dr. Rosenthal, has only attempted to calculate the impact of "detailing" (by all defendants, in the aggregate) on opioid shipments.[4] But Dr. Rosenthal acknowledges that "manufacturers ***will not detail*** physicians ***for generics***."[5] In short, Plaintiffs simply have no individual or aggregate evidence of causation as to the Generic Manufacturers.

II. ARGUMENT

Plaintiffs concede that any failure-to-disclose claims against Generic Manufacturers are preempted and that they are not asserting any such claims.[6] Likewise, Plaintiffs concede that they are not seeking to hold Generic Manufacturers liable merely for selling FDA-approved medicines in a market created by the alleged false marketing of others, or even because they now have a larger market share.[7] Such claims are preempted too. *See Mutual Pharm. Co. v. Bartlett*, 570 U.S. 472, 488 (2013); *In re Darvocet*, 756 F.3d 917, 925 (6th Cir. 2014); *see also* Mem. at 11-13.

---

[4] *See* Mem. in Support of Defs.' Mot. to Exclude Dr. Rosenthal ("Rosenthal Daubert"), Dkt. No. 1913-1, at 1 (citing Rosenthal Report, Dkt. No. 1913-4, at ¶ 56 and Rosenthal Dep., Dkt. No. 1913-5, at 44:11–19.)

[5] Rosenthal Dep., Dkt. No. 1913-5, at 197:23–198:4 (emphasis added).

[6] Opp. at 26 ("[T]he Supreme Court in *Mensing* concluded state law claims that require a generic manufacturer to add new safety information to its label or to disseminate such new information without a corresponding change to the approved brand label are preempted. *Mensing*, 564 U.S. at 615."); *id*. at 26-27 ("Plaintiffs ***are not*** claiming Defendants should have changed their generic drug labels or should have affirmatively disseminated information not already contained in the approved labels.") (emphasis added).

[7] *See* Opp. at 2 ("Defendants' argument they cannot be held liable for selling pills into a market created by alleged false marketing of brand name prescription medicines by other[s] . . . [i]s belied by the facts: it was not only other

Given these necessary concessions, Plaintiffs effectively admit that to succeed on a claim against any Generic Manufacturer they must present evidence of affirmative false marketing by that Generic Manufacturer.[8] To meet this summary judgment burden, Plaintiffs must show evidence as to ***each*** Generic Manufacturer—and cannot group defendants together. *See, e.g.*, *Sindelir v. R.J. Corman Const.*, 1993 WL 533119, at *3 (6th Cir. Dec. 23, 1993) (affirming summary judgment for defendants where plaintiff failed to present "sufficient evidence of tortious conduct on the part of ***each*** defendant" (emphasis added).)[9] Indeed, Plaintiffs must show that: (a) each Generic Manufacturer (not some other entity) engaged in false marketing in the Counties; and (b) such false marketing caused harm to the Counties. *See, e.g., Pang v. Minch*, 559 N.E.2d 1313, 1324 (Ohio 1990) (to defeat summary judgment plaintiff must present evidence showing that "the conduct of ***each defendant*** was a substantial factor in producing the harm" (citation omitted, emphasis added).) Plaintiffs' Opposition ignores these well-settled principles.

A. Plaintiffs' Evidence Shows That Generic Manufactures Did Not And Do Not Promote The Safety Or Efficacy Of Their Generic Medicines.

Plaintiffs' Opposition fails to identify a single statement about a generic opioid medicine to any Ohio doctor or patient made by a single Generic Manufacturer. They cite no call notes. No detailing records. No plans to market the safety or efficacy of a generic medicine. No communications with any Ohio doctors. Because there are none. Instead, Plaintiffs try to "bootstrap" a theory of liability as to Generic Manufacturers by lumping each Generic

companies that created the extraordinary market for opioid drugs, these Defendants substantially contributed to it. . . . They embarked on a decades-long coordinated, aggressive, and misleading marketing campaign to establish and grow the prescription opioid market.")

[8] Opp. at 1 ("[Generic] Defendants engaged in aggressive and misleading marketing; and claims based on that conduct which are not predicated, on a claim of failure to change product labeling, are not preempted."); *id.* at 26 ("Plaintiffs contend that [Generic] Defendants voluntarily made affirmative marketing representations beyond the labels that were false and misleading.")

[9] Even Plaintiffs acknowledge this legal rule. Pls.' Mot. to Sever, Dkt. No. 2099, at 2 (Plaintiffs must "prove their claims against each individual defendant based upon each defendant's alleged wrongdoing").

Manufacturer with brand manufacturers and/or brand medicines.[10] This requires summary judgment as a matter of law with respect to any claims based upon the marketing of generic medicines.

Actavis Generic Defendants. Plaintiffs do not present any evidence that any Actavis Generic Defendant marketed the safety or efficacy of its generic medicines, much less did so in a false or misleading manner. Instead, Plaintiffs rely on improper generalized allegations regarding the marketing activities of an undefined, conglomerate group of companies labeled "Allergan." Opp. at 17-21. These generalized allegations as to "Allergan" are insufficient to carry Plaintiffs' burden as to ***each*** (or any) of the eleven Actavis Generic Defendants at summary judgment.

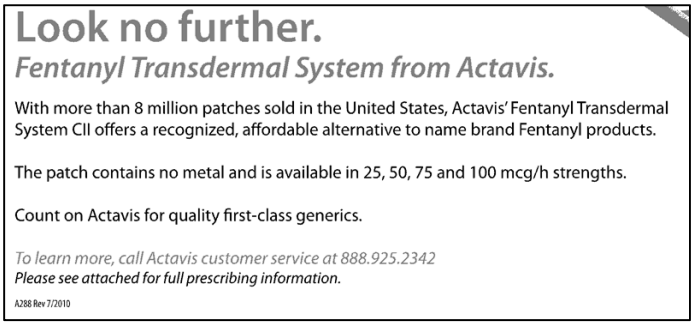
Worse yet, as supposed proof that "Allergan" marketed the safety and efficacy of its generic medicines, Plaintiffs point exclusively to testimony and exhibits from the depositions of Jinping McCormick, Jennifer Altier, and Douglas Boothe. Opp. at 17-21. But as reflected in Exhibits A-C to the Declaration of Steven A. Reed ("Reed Decl."), ***all*** of these witnesses testified to the opposite: the Actavis Generic Defendants did not market the safety or efficacy of their generic medicines. Although Plaintiffs argue that the Actavis Generic Defendants occasionally marketed their generic medicines through wholesalers and by contacting pharmacies and physicians using sales representatives who had previously marketed the branded opioid medicine Kadian, ***all*** of these witnesses repeatedly testified that these marketing efforts were limited to noting the ***availability*** of the generic medicines—not their safety, efficacy, or benefits.[11]

[10] Plaintiffs' "bootstrap" theory of liability as to Generic Manufacturers is inconsistent with Ohio law's requirement that each Defendant can be held liable only for its own unlawful conduct, *Sutowski v. Eli Lilly & Co.*, 696 N.E.2d 187, 190 (Ohio 1998) (notion that "manufacturers are required to pay or contribute to payment for injuries which their product may not have caused … is not the law in Ohio"). It appears to be nothing more than an afterthought merely because they have discovered that Generic Manufacturers now have a larger market share.

[11] Deposition of Jinping McCormick, Dkt. No. 1981-14, at 74:15–75:2 (testifying that generic oxymorphone was marketed "just to make physicians and the pharmacists aware of the introduction of a generic alternative to the brand. So it's awareness marketing); Deposition of Jennifer Altier ("Altier Dep."), Dkt. No. 1974-6, at 319:16–18 ("[T]he ***only*** information [the Kadian sales force was] providing was that it was available." (emphasis added)); Deposition of

This undisputed testimony is supported by the very materials on which Plaintiffs rely. Each shows that the Actavis Generic Defendants only advertised the availability and bioequivalence of their generic medicines. By way of example:

- **Opp. Ex. 64 (generic fentanyl transdermal ad)**: The instructions make clear that the ad "should promote how the product is different from other generics, or Actavis's manufacturing capabilities ***rather than the product's benefits to the consumer***." Opp. Ex. 64 at 3. The advertisement is entirely consistent with this guidance:


Look no further.

Fentanyl Transdermal System from Actavis.

With more than 8 million patches sold in the United States, Actavis' Fentanyl Transdermal System CII offers a recognized, affordable alternative to name brand Fentanyl products.

The patch contains no metal and is available in 25, 50, 75 and 100 mcg/h strengths.

Count on Actavis for quality first-class generics.

To learn more, call Actavis customer service at 888.925.2342
Please see attached for full prescribing information.

A288 Rev 7/2010

  Plaintiffs argue that "Allergan said ***nothing*** about the risk of addiction or overdose" in this ad (Opp. at 20 (emphasis in original)), but, in fact, the ad makes clear that the full prescribing information is attached, including the FDA-approved labels that communicate warnings about the risk of addiction and overdose.[12] Moreover, the Hatch-Waxman Act's "duty of sameness" prohibited "Allergan" from communicating anything further about this generic opioid medicine. *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 615 (2011).

- **Opp. Ex. 66 (oxymorphone ad)**: This document makes clear that it pertains to an "***awareness*** campaign" and, accordingly, the goals should be to communicate "to pharmacists" that: (1) "[g]eneric oxymorphone ER 15mg and 7.5mg are available [to] fill the gap since brand discontinues these two strengths" and (2) to "provide a financial incentive to get this bottle on the shelf" via rebates. Opp. Ex. 66 at 4-5. The safety or efficacy of these generic medicines is not mentioned—and no such statements were made.

Of course, there is nothing unlawful or fraudulent about advertising the commercial availability of FDA-approved generic medicines—whether to physicians, pharmacies, or anyone else.

Plaintiffs also argue that "Allergan" had a "brand" sales force that marketed the safety and efficacy of Kadian. *See* Opp. at 17 (citing Altier Dep. Ex. 3.) But Kadian is a brand medicine—

Douglas Boothe, Dkt. No. 1975-6, at 150:2–9 (testifying that the purpose of generic marketing is "to announce a product approval or a product becoming available.")

[12] *See* Reed Decl. Ex. D.

not a generic. *Id.* at 17 n. 22. It is not at issue in this motion. Indeed, Plaintiffs improperly rely upon documents about Allergan's marketing of Kadian (such as an August 26, 2011 email string) dated more than ***three*** months before the generic version of Kadian had even become available[13]—and well outside the limitation period. Opp. at 13 (citing Opp. Ex. 58). Notably, Plaintiffs do not identify any statements made by an Actavis Generic Defendant regarding a single generic medicine (including generic Kadian) in any of the Counties or elsewhere. There is none.

Teva USA. Plaintiffs do not dispute that prior to 2011 Teva USA sold ***only*** generic opioid medicines.[14] Nor do Plaintiffs present any evidence that Teva USA falsely marketed the safety or efficacy of any of its generic medicines—either before or after October 2011. Indeed, Teva USA has not and does not promote its generic medicines, whether through detailing or third parties.[15] Plaintiffs attempt to meet their burden as to Teva USA by relying on the conduct of Cephalon (an entirely distinct company) and various third parties, and then calling them all "Teva." Opp. at 22-25. In fact, there is no specific mention of Teva USA. Plaintiffs' generalized allegations are insufficient to carry Plaintiffs' burden as to Teva USA at summary judgment.

Plaintiffs' evidence confirms this failure. Virtually all of the exhibits Plaintiffs rely upon relate to third-party publications funded by Cephalon (not Teva USA), and often before Teva USA had ***any affiliation*** with Cephalon (before October 2011). For example, Cephalon—not Teva USA—provided the financial grant to publish the 2008 Continuing Medical Education ("CME") program, "Persistent and Breakthrough Pain." Opp. at 25 n. 39 (citing Opp. Ex. 94) ("Supported by an educational grant from Cephalon, Inc."). Likewise, it was Cephalon that published a 2004 brochure about breakthrough pain. Opp. at 25 n. 41 (citing Opp. Ex. 96) ("2004 Cephalon, Inc.

[13]*See* Reed Decl. Ex. E, *Allergan – News*, "Watson Launches Generic Kadian," November 10, 2011, accessible at https://www.allergan.com/news/news/thomson-reuters/watson-launches-generic-kadian-r
[14] Dkt. No. 1860-16 (Declaration of Christine Baeder, Head of Generics at Teva USA), at ¶ 3.
[15] Deposition of Christine Baeder, Dkt. No. 1974-8, at 417:2-419:5; Dkt. No. 1749-16 (Baeder Declaration), at ¶ 4.

All rights reserved.") Similarly, Plaintiffs concede that the 2007 patient toolkit was funded by Cephalon—not Teva USA. Opp. at 24 (citing Opp. Ex. 86) ("Cephalon—ESP Patient Tool Kit—All About Opioids"). Plaintiffs even argue that "Teva" is responsible for opioid-related statements contained in the American Pain Foundation's ("APF") *Exit Wounds* publication, but that same document shows that Cephalon—not Teva USA—sponsored that third-party publication. Opp. at 23 n. 31 (citing Opp. Ex. 77) ("Teva Company: Cephalon Inc.")[16] Plaintiffs' claims against Cephalon (which never sold generic opioids) fail for other reasons, but those claims are not the subject of this Motion.

The remaining evidence that Plaintiffs rely upon relates to the marketing of brand medicines only—and not the generic medicines at issue in this Motion. For example, Plaintiffs cite an analysis of professional organizations from a third-party vendor, but that document was created in connection with Fentora (a brand medicine manufactured by Cephalon), not any of Teva USA's generic medicines. Opp. at 23 (citing Opp. Ex. 73) ("highlighting FENTORA's new sublingual administration"). The same is true of "Teva's" activities at the Painweek conference, which involved Fentora and did not mention any of Teva USA's generic medicines. Opp. at 25 n. 40 (citing Opp. Ex. 95) ("Fentora Product Theater"). Likewise, the chart Plaintiffs attach as supposed proof of "Teva's" speaker programs for generic medicines organizes speakers based on "Fentora Class" and "Fentora Programs;" it does not mention generics because there is no and has been no promotion of their safety or efficacy. Opp. at 25 n. 37 (citing Opp. Ex. 95.)

[16] Summary judgment is appropriate with respect to any third-party statements for yet another reason: Plaintiffs offer no evidence that Teva USA or any Generic Manufacturer controlled such statements. *See McWilliams v. S.E., Inc.*, 581 F. Supp. 2d 885, 893 (N.D. Ohio 2008) (holding that a defendant cannot be liable for a third-party statement where it is not established that the third party acted as the defendant's agent with respect to the challenged statement); *Taylor v. Checkrite, Ltd.*, 627 F. Supp. 415, 416-17 (S.D. Ohio. 1986) (holding that the "central factor" in determining whether an agency relationship exists is the "right of control" vested in the principal); *see also* Mfr. Dfs.' Mot. for Summ. J. for Pls.' Failure to Offer Proof of Causation, Dkt. No. 1894.

Lastly, Plaintiffs rely upon entirely irrelevant documents—none of which show that Teva USA falsely marketed the safety or efficacy of its generic medicines in Ohio. These include a webpage detailing the history of the Teva corporate family (Opp. Ex. 70), a catalog of invoices belonging to different companies in the Teva corporate family (Opp. Ex. 88), a catalog of coupons and rebates offered by Teva USA to physicians (Opp. Ex. 91), and website pages from a campaign entitled "Pain Matters," which contained information about chronic pain and opioid abuse and misuse (Opp. Ex. 84).[17] Nothing in these documents shows or suggests that Teva USA made any false or misleading statement regarding any of its generic medicines. There is no such evidence.

Mallinckrodt. Plaintiffs concede that Mallinckrodt did not promote its generic opioid products to physicians. Plaintiffs' opposition identifies no evidence of ***any*** promotion of Mallinckrodt's generic opioid products to physicians, much less ***false or misleading*** promotion.[18] Mallinckrodt's generics business has no sales force that calls on physician offices. Nor did it use key opinion leaders, speaker programs, or third-party groups to promote the therapeutic benefits of its generic products to physicians.[19] Plaintiffs do not and cannot dispute this.

Instead, Plaintiffs resort to examples of Mallinckrodt's alleged distribution of ***unbranded*** materials. But Plaintiffs have presented no evidence that these materials were intended to support sales of Mallinckrodt's generic opioid products, or that these materials led any doctor to prescribe Mallinckrodt's generic opioid products—or any opioid products at all for that matter. In short, the record simply offers no evidence that Mallinckrodt promoted its generic products to physicians at all, much less in a misleading or false manner.

---

[17] The website also presented factual information regarding Prescription Drug Monitoring Programs ("PDMP") and Risk Evaluation and Mitigation Strategies ("REMS"). Opp. Ex. 84. It contained numerous warnings about the high risk of addiction, including death, related to opioids. *Id.*

[18] Deposition of Kevin Verdestrasse, Dkt. No. 1985-8, at 144:21–145:5.

[19] Deposition of Ginger Collier, Dkt. No. 1976-4, at 253:13–19; Deposition of Lisa Cardetti, Dkt. No. 1975-17, at 232:3–14.

Instead of proffering evidence that Mallinckrodt promoted generic opioid medicines to physicians, Plaintiffs attempt to distract the Court with irrelevant allegations about trade shows and pharmacists—aspects of Mallinckrodt's business that are not the subject of this Motion. Evidence regarding trade shows might reflect exposure to groups, like distributors or pharmacists, "who often make product ***purchasing*** decisions," Opp. at 8, but it says nothing about the relevant inquiry: marketing to those who make ***prescribing*** decisions. Mallinckrodt sells generic opioid medicines to wholesalers, distributors, and retail pharmacies, and competes for market share in those spaces. Mem. at 6-7. Plaintiffs' cannot plausibly cite Mallinckrodt's attendance at trade shows as evidence of its promoting its generic products to physicians: A prescription necessarily exists before a pharmacist can fill it. What's more, Plaintiffs' insinuation that pharmacists influenced physicians' prescribing decision is unsupported by any record evidence.

Finally, to the extent Mallinckrodt distributed unbranded marketing materials to pharmacists at trade shows (something that could not form the basis for Plaintiffs' generic false marketing claim, as just explained), Plaintiffs provide no evidentiary support at all for their assertions that Mallinckrodt's materials contained "multiple misleading statements." Opp. at 10. Plaintiffs simply list a handful of statements in their opposition and baldly assert that they are "misleading," "false," and "misrepresentations," without providing any support for those assertions. *See, e.g.*, Opp. at 7-8 ("With older adults, start dose low, go slow, but go!"); *id.* at 10 ("It is currently recommended that every chronic pain patient suffering from moderate to severe pain be viewed as a potential candidate for opioid therapy.").

At this stage of the proceeding, these statements are not rendered false or misleading simply by Plaintiffs' say so, or by their reference to Mallinckrodt's awareness of the risk of opioid addiction. And, in fact, Plaintiffs' opposition ignores undisputed record evidence affirmatively

demonstrating that certain of these statements are indeed ***true***. The FDA, for example, has stated that addiction rarely occurs from the use of opioid medicines. Deposition of Matthew Perri, Dkt. No. 1983-5, at 483:19–24) ("According to the National Institutes of Health, studies have shown that properly managed medical use of opioid analgesic compounds (taken exactly as prescribed) is safe, can manage pain effectively, and ***rarely causes addiction***.") (emphasis added)).

Because Plaintiffs have presented no evidence that any physician was misled by Mallinckrodt to prescribe a Mallinckrodt generic opioid, summary judgment should enter in Mallinckrodt's favor on Plaintiffs' generic false marketing claims.

Par Defendants. Apart from a passing reference to "Par" in a heading, *see* Opp. at 11, Plaintiffs' Opposition makes no mention of Par Pharmaceutical, Inc. or Par Pharmaceutical Companies, Inc. Plaintiffs cite no evidence suggesting that either of these defendants ever engaged in false or misleading marketing with respect to any opioid medicine. It is clear Plaintiffs cannot create a genuine issue of material fact for trial on this issue. Rule 56(a) requires the entry of summary judgment in the Par Defendants' favor on Plaintiffs' false marketing theories.

Endo Defendants. The Endo Defendants—Endo Pharmaceuticals Inc. and Endo Health Solutions Inc.—are likewise entitled to summary judgment as to all claims based on the allegedly false marketing of generic opioid medicines. Plaintiffs do nothing to create a genuine issue of material fact on this issue. Plaintiffs' reference to branded (or legacy branded) products like Opana ER or Percocet, Opp. at 11-12, are all beside the point: they are not the generic medicines at issue, and thus not encompassed within the scope of this Motion. As to generic medicines specifically:

- Plaintiffs assert that Endo began selling a generic version of OxyContin in 2006, *id.* at 12, but they identify no statements (false or otherwise) relating to this product.
- Plaintiffs allege that Endo engaged in "some direct promotion of generics," *id.*, but the very deposition testimony Plaintiffs cite for this proposition shows the opposite: that "the generic [d]id not get marketed to physicians." *Id.* (citing Deposition of George Stevenson).

"[S]ome sales effort" directed to "retailers and wholesalers," *id.*, does not suggest that any generic product was falsely marketed to physicians or patients.

- At most, the exhibits Plaintiffs cite show only that Endo provided information about its generic medications' availability, price, and bioequivalence to pharmacists and wholesalers. *See* Opp. Ex. 54 (providing information to pharmacies about pricing of generic morphine sulfate extended-release tablets); Opp. Ex. 30 at ENDO-OPIOID_MDL-04814978 ("[o]rder [morphine sulfate extended-release tablets] from your wholesaler today").

Plaintiffs do not identify evidence of any marketing by the Endo Defendants regarding the safety or efficacy of any of their generic opioid medicines. Instead, Plaintiffs point to documents that only serve to confirm that Endo did ***not*** engage in such marketing for those medicines, much less engage in marketing that was false or misleading.

Plaintiffs baldly assert that "[m]any of Endo's marketing materials directed to physicians" misleadingly "asserted the risk of addiction from opioid use was low," Opp. 15, incorrectly implying that such materials were used to market generic products. Plaintiffs cite nothing from the record that supports this assertion. As an initial matter, nothing in the two "marketing materials" Plaintiffs reference was false or misleading. But, in any event and for purposes of this Motion, those materials, both patient-directed brochures, were distributed in connection with branded and legacy branded medicines Opana ER and Percocet and refer only to branded opioid medicines. *See* Opp. 15; Opp. Ex. 51. Plaintiffs offer no evidence that any prescriber relied on those brochures in writing ***any*** opioid prescription, let alone any generic prescriptions. Plaintiffs similarly have nothing to point to that would show any patient relied on them either. Indeed, the brochures expressly disclaim that they "replace talking with [the patient's] healthcare provider about [the patient's] treatment options." Opp. Ex. 51 at 1; *see also* Opp. Ex. 52 at ENDO-CHI_LT-00084050.

Plaintiffs' citation to a single internal sales training document, created in connection with Endo's ***branded*** oxymorphone medicine, Opana ER, is similarly flawed. That document expressly

states that it is "For Sales Training Background Purposes Only" and that it "is not to be used in selling efforts or distributed to anyone outside Endo Pharmaceuticals." Opp. Ex 53 at ENDO-OPIOID_MDL-02150882, ENDO-OPIOID_MDL-02150883. Again, Plaintiffs offer nothing even suggesting that the passages from this document referenced in their Opposition (*see* Opp. 15, 16) were ever used to promote any opioid medicine, let alone any ***generic*** medicine.

Plaintiffs Opposition is replete with similar references to irrelevant documents (many of which pre-date 2006) that create no genuine issues about promotion by Endo's generics business. Plaintiffs rely, for example, on citations to numerous internal documents (*e.g.*¸Opp. Exs. 29, 31, 32, 35), documents concerning medical education programs conducted by third parties independent of Endo (*e.g.*, Opp. Exs. 36, 41), and summaries of annual sales data (Opp. Ex. 45), but fail to connect any of those documents to evidence of actual promotion by Endo of its generic opioid medicines to physicians. These documents only underscore the obvious—after months of discovery, Plaintiffs cannot create a genuine issue that Endo's generics business promoted the safety or efficacy of its opioid medicines.

B. <u>Plaintiffs Offer No Evidence Of Causation As To Any Generic Manufacturer</u>.

It is undisputed that causation is an element of Plaintiffs' false marketing claims.[20] But Plaintiffs completely ignore their burden to provide evidence in support of this element as to the Generic Manufacturers. *See, e.g., Everson v. Leis*, 556 F.3d 484, 496 (6th Cir. 2009) ("failure to present any evidence to counter a well-supported motion for summary judgment alone is grounds for granting the motion"). In fact, Plaintiffs do not even attempt to identify any such evidence.

[20] *See In re ClassicStar Mare Lease Litig.*, 727 F.3d 473, 487 (6th Cir. 2013) (but for and proximate causation are elements of a RICO claim); *Berisford v. Sells*, 331 N.E.2d 408, 409 (Ohio 1975) (same as to negligence claim); *City of Cincinnati v. Deutsche Bank Nat'l Tr. Co.*, 863 F.3d 474, 477 (6th Cir. 2017) (same as to Ohio's common law public nuisance); *City of Cleveland*, 615 F.3d 496, 503 (6th Cir. 2010) (same as to Plaintiffs' OCPA claims).

Nor can Plaintiffs meet that burden, given that their chief causation expert, Dr. Rosenthal, has confirmed that Plaintiffs have no causation theory as to the Generic Manufacturers. Dr. Rosenthal testified that her causation modeling is based upon "detailing [by sales representatives] as the measure of marketing." Dkt. No. 1913-5, at 167:3-7; *see also* Pls.' Opp. to Rosenthal Daubert, Dkt. No. 2176, at 11 (Rosenthal's "model is intended to, and does, capture the average effect of all detailing.") She further assumes (improperly) that all "detailing" is false. Dkt. No. 2176 at 13. But Dr. Rosenthal made clear that "***manufacturers will not detail physicians for generics***," Dkt. No. 1913-5 at 197:23-198:4 (emphasis added), and Plaintiffs' own proffered evidence establishes that any communications with physicians involving generic medicines concerned their availability and bioequivalence—that is, no promotional detailing and certainly no false detailing. Thus, her "aggregate" causation model—even if it were valid (and it is not)—says nothing about Generic Manufacturers.

Nor do Plaintiffs attempt to introduce any individualized evidence showing that any Ohio prescriber or patient received or heard any allegedly false marketing by any Generic Manufacturers—much less relied upon any such marketing to write a medically inappropriate prescription, as opposed to exercising her own independent medical judgment.[21] Plaintiffs, in fact, have not identified a single interaction between any Generic Manufacturer and any Ohio physician regarding generic medicines. Because Plaintiffs offer no causation model and no causation evidence as to the Generic Manufacturers, summary judgment is appropriate for this reason too.

III. CONCLUSION

For the foregoing reasons, the Court should grant Generic Manufacturers' motion for summary judgment on all false marketing claims pertaining to generic medicines.

[21] Ohio doctors must be aware of the labels and risks of the medicines that they prescribe, and must evaluate the individualized risks for each patient prescribed an opioid medicine. Ohio Admin. Code Ch. 4731-29-01.

Dated: August 16, 2019

Respectfully submitted,

/s/ Steven A. Reed
Steven A. Reed
Eric W. Sitarchuk
Rebecca J. Hillyer
MORGAN, LEWIS & BOCKIUS LLP
1701 Market Street
Philadelphia, PA 19103-2921
Telephone: +1.215.963.5000
Facsimile: +1.215.963.5001
steven.reed@morganlewis.com
eric.sitarchuk@morganlewis.com
rebecca.hillyer@morganlewis.com

Nancy L. Patterson
MORGAN, LEWIS & BOCKIUS LLP
1000 Louisiana Street, Suite 4000
Houston, TX 77002-5005
Tel: (713) 890-5195
nancy.patterson@morganlewis.com

Brian M. Ercole
MORGAN, LEWIS & BOCKIUS LLP
200 S. Biscayne Blvd., Suite 5300
Miami, FL 33131-2339
Tel: (305) 415-3000
brian.ercole@morganlewis.com

Attorneys for Teva Pharmaceuticals USA, Inc., Watson Laboratories, Inc., Actavis LLC, Actavis Pharma, Inc. f/k/a Watson Pharma, Inc., Warner Chilcott Company, LLC, Actavis South Atlantic LLC, Actavis Elizabeth LLC, Actavis Mid Atlantic LLC, Actavis Totowa LLC, Actavis Kadian LLC, Actavis Laboratories UT, Inc. f/k/a Watson Laboratories, Inc.-Salt Lake City, and Actavis Laboratories FL, Inc., f/k/a Watson Laboratories, Inc.-Florida

/s/ Brien T. O'Connor (consent)
Brien T. O'Connor
Andrew J. O'Connor
ROPES & GRAY LLP
Prudential Tower
800 Boylston St.
Boston, MA 02199-3600
(617) 235-4650
Brien.O'Connor@ropesgray.com
Andrew.O'Connor@ropesgray.com

Attorneys for Defendants Mallinckrodt LLC and SpecGx LLC, and appearing specially for Mallinckrodt plc[22]

/s/ Daniel G. Jarcho (consent)
Daniel G. Jarcho
D.C. Bar No. 391837
ALSTON & BIRD LLP
950 F Street NW
Washington, DC 20004
Telephone: (202) 239-3254
Facsimile: (202) 239-333
E-mail: daniel.jarcho@alston.com

Cari K. Dawson
Georgia Bar No. 213490
Jenny A. Hergenrother
Georgia Bar No. 447183
ALSTON & BIRD LLP
1201 West Peachtree Street NW
Atlanta, GA 30309
Tel.: (404) 881-7000
Fax: (404) 881-7777
cari.dawson@alston.com
jenny.hergenrother@alston.com

Attorneys for Defendant Noramco, Inc.

/s/ Sean O. Morris (consent)
Sean O. Morris
ARNOLD & PORTER KAYE SCHOLER LLP
777 S. Figueroa St., Suite 4400
Los Angeles, CA 90017
Tel: (213) 243-4000
sean.morris@arnoldporter.com

Jonathan L. Stern
ARNOLD & PORTER KAYE SCHOLER LLP
601 Massachusetts Ave. NW
Washington, DC 20001
Tel: (202) 942-5000
jonathan.stern@arnoldporter.com

Attorneys for Endo Pharmaceuticals Inc., Endo Health Solutions Inc., Par Pharmaceutical, Inc., and Par Pharmaceutical Companies, Inc. (incorrectly named as "Par Pharmaceutical Companies, Inc. f/k/a Par Pharmaceutical Holdings, Inc.")

[22] Mallinckrodt plc is an Irish company that is not subject to and contests personal jurisdiction for the reasons explained in its motion to dismiss for lack of personal jurisdiction. It is specially appearing to join this motion, and, thus, does not waive and expressly preserves its personal jurisdiction challenges.

CERTIFICATE OF SERVICE

The undersigned hereby certifies that on August 16, 2019, the foregoing was filed using the Court's CM/ECF filing system and will be served via the Court's CM/ECF filing system on all attorneys of record.

/s/ Steven A. Reed
Steven A. Reed